

**Plaintiffs' Memorandum in Opposition
to Joint Motion for Summary
Judgment for Failure to Prove Fault
Element of Public Nuisance Claims**

Ex 47 – Kelly Tr. Excerpts

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - -

5
6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :

13 - HIGHLY CONFIDENTIAL -

14 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

15 - - -

16 May 10, 2019

17 - - -

18 Videotaped deposition of
19 PATRICK KELLY, taken pursuant to notice,
20 was held at the offices of Baron & Budd,
21 600 New Hampshire Avenue, NW, Washington,
22 D.C., beginning at 8:58 a.m., on the
23 above date, before Michelle L. Gray, a
24 Registered Professional Reporter,
 Certified Shorthand Reporter, Certified
 Realtime Reporter, and Notary Public.

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 GOLKOW LITIGATION SERVICES
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 deps@golkow.com

1 BY MR. PIFKO:

2 Q. All right. So you
3 understand that you're here to answer
4 questions and your counsel may object
5 from time to time. But unless he
6 instructs you not to answer, you're still
7 going to answer the question.
8 Understood?

9 A. Understood.

10 Q. Okay. So you understand
11 that you're here in your individual
12 capacity but you're also here as the
13 official representative of HDA with
14 respect to certain topics, correct?

15 A. I understand that, yes.

16 Q. Okay. And so that means
17 when you answer within those topics,
18 you're answering as if you are the HDA.
19 Do you understand that?

20 A. I understand that.

21 Q. Okay. I'm going to hand you
22 a copy of the notice.

23 (Document marked for
24 identification as Exhibit

1 A. I have.

2 Q. Okay. This is a document
3 from Anita Ducca to you dated October 31,
4 2016. Agreed?

5 A. Yes.

6 Q. Okay. Who is Anita Ducca?

7 A. Anita Ducca is the senior
8 vice president of regulatory affairs for
9 Healthcare Distribution Alliance.

10 Q. She reports to you?

11 A. She does.

12 Q. How long have you been with
13 the HDA?

14 A. I joined in January of 2011.

15 Q. The HDA is an organization
16 that acts on behalf of its members,
17 correct?

18 A. That's correct.

19 Q. Your members include the,
20 what we refer to in the case as the big
21 three distributors, Cardinal Health,
22 AmerisourceBergen, and McKesson; is that
23 correct?

24 A. In addition to -- in

1 addition to 29 other companies, yes.

2 Q. Okay. And you also have
3 manufacturers who are members of the
4 organization, correct?

5 A. They are in a different
6 membership category, yes.

7 Q. But they are still members?

8 A. They are members in a
9 different category.

10 Q. Okay. Mallinckrodt is a
11 member?

12 A. In the affiliate member
13 category I believe so, yes.

14 Q. Okay. Purdue?

15 A. I believe so, in the -- in
16 the affiliate member category.

17 Q. Janssen and Janssen?

18 A. Johnson & Johnson?

19 Q. Sorry. Janssen -- Janssen
20 or Johnson & Johnson?

21 A. Yes, I believe in the
22 affiliate member category.

23 Q. Actavis?

24 A. Actavis, I believe so in the

1 affiliate member category.

2 Q. Teva?

3 A. I believe so.

4 Q. Endo?

5 A. I believe so.

6 Q. Okay. The HDA doesn't act
7 on it -- on its own, it acts in the
8 interest of its members and on behalf of
9 its members, correct?

10 MR. WEINSTEIN: Objection.
11 Objection to form.

12 Go ahead. You've just got
13 to give me a moment to object.

14 THE WITNESS: Sorry, I'm
15 sorry, I apologize.

16 We act on behalf of our core
17 members which are the distributor
18 members.

19 BY MR. PIFKO:

20 Q. Okay. You have a board,
21 correct?

22 A. We do.

23 Q. The board membership always
24 includes members from the big three,

1 AmerisourceBergen, McKesson, and Cardinal
2 Health, correct?

3 A. In addition to the 29 other
4 members, yes.

5 Q. Okay. But the board always
6 has somebody from those companies on it?

7 A. That's correct.

8 Q. And then there's an
9 executive committee as well, correct?

10 A. That is correct.

11 Q. And what's the makeup of the
12 executive committee?

13 A. The --

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: The executive
17 committee is seven members, three
18 members from the big three,
19 AmerisourceBergen, McKesson, and
20 Cardinal have a standing position
21 on the executive committee.

22 And then there are four
23 other positions that are other
24 member companies that filter

1 Q. This is another e-mail from
2 Ms. Ducca. The subject is HDMA DEA
3 strategy meeting, availability response
4 requested on alternative dates. It's
5 dated September 26, 2007. And it's got
6 another e-mail below also from Ms. Ducca
7 dated September 25, 2007.

8 MS. WICHT: Can you just
9 hold on until we have the
10 document --

11 MR. PIFKO: Yeah, no
12 problem. I was just going to -- I
13 was going to read the Bates label.

14 Bates label is
15 CAH_MDL_PRIORPROD_DEA07_00877471
16 through 473.

17 BY MR. PIFKO:

18 Q. So take a minute to review
19 it and let me know when you're ready.

20 A. Okay.

21 Q. All right. So on the first
22 page here again it's talking about
23 setting up some -- some meetings.

24 On the first page at the

1 bottom of her -- Anita Ducca's e-mail,
2 dated September 25, 2007.

3 Do you see that?

4 A. I do.

5 Q. Okay. She says, "Dear HDMA
6 committee members." So, the HDMA
7 committee members, that includes all
8 members?

9 MR. WEINSTEIN: Objection to
10 form.

11 THE WITNESS: In this
12 instance it appears to be the
13 regulatory affairs committee and
14 the federal government affairs
15 committee.

16 BY MR. PIFKO:

17 Q. And it's cc'd to the
18 government public policy committee as
19 well?

20 A. Government public policy
21 council.

22 Q. Oh, council. Okay.

23 Those all include
24 representatives from all the HDA

1 distributor members?

2 A. That participate in those
3 committees, yes.

4 Q. Okay. And again, that --
5 those include members from the big three
6 distributors, correct?

7 A. Yes.

8 Q. So she says here, "Given the
9 intensity and impact of the Drug
10 Enforcement Administration's recent
11 actions, and the concerns expressed by
12 HDMA's executive committee last week,
13 HDMA recommends developing a
14 comprehensive DEA strategy."

15 Do you see that?

16 A. I do.

17 Q. So at this time, the HDA on
18 behalf of its members was developing a
19 comprehensive DEA strategy as a result of
20 what they understood to be an -- intense
21 actions from the DEA; is that correct?

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Yes, that is

1 correct.

2 BY MR. PIFKO:

3 Q. And then if you go to the
4 second page of the document, she outlines
5 some of the topics of discussions.

6 Do you see that?

7 A. I do.

8 Q. Okay. So she says, "Our
9 initial thoughts are" -- I'm on the
10 second paragraph at the top there. Are
11 you with me?

12 A. Yes, I am.

13 Q. She says, "Our initial
14 thoughts are to review the major DEA
15 issues."

16 Do you see that?

17 A. I do.

18 Q. And then she has in
19 parentheses what those issues are, right?

20 A. Yes.

21 Q. And one of them is
22 suspicious orders, correct?

23 A. Yes.

24 Q. And then she says, she wants

1 to develop a specific policy and
2 positions and supporting information for
3 those issues.

4 Do you see that?

5 A. Yes.

6 Q. As well as an overall
7 strategy for identifying solutions.

8 Do you see that?

9 A. I do.

10 Q. "We would also
11 comprehensively assess HDMA's role in
12 future DEA interactions."

13 Do you see that?

14 A. I do.

15 Q. I said that correctly?

16 A. Yes, you did.

17 Q. Okay. So then she says,
18 "Specific topics could include." And
19 there are several bullet points here.

20 Do you see that?

21 A. I do.

22 Q. So she says, "For suspicious
23 orders," she says, are -- I'm reading the
24 second bullet point. "Are there

1 alternatives we can propose to DEA, or
2 specific objections we should raise?
3 What supporting information exists? Can
4 we develop a strategy for DEA's concerns?
5 Who should be involved?"

6 Do you see that?

7 A. Yes.

8 Q. So, again, there was a
9 discussion within the HDMA and its
10 members at this time about a strategy for
11 communicating with DEA, correct?

12 A. Yes.

13 Q. Another -- the
14 second-to-last bullet point, she has
15 here, she says, "What, if any, legal
16 options do we have to address all of the
17 above?"

18 Do you see that?

19 A. I do.

20 Q. So in addition to a DEA
21 strategy, HDMA and its members at this
22 time were also evaluating legal options
23 they might have to address these issues,
24 correct?

1 MR. WEINSTEIN: Objection to
2 form.

3 THE WITNESS: According to
4 this, yes.

5 BY MR. PIFKO:

6 Q. You don't have any reason to
7 dispute the accuracy of this?

8 A. I don't.

9 (Document marked for
10 identification as Exhibit
11 HDA-Kelly-5.)

12 BY MR. PIFKO:

13 Q. I'm handing you what's
14 marked as Exhibit 5. It is a single-page
15 e-mail. It's Bates-labeled
16 HDA_MDL_000213427. Take a minute to
17 review it and let me know when you're
18 ready.

19 A. Okay.

20 Q. There's two e-mails in here,
21 only really one of substance. The
22 substantive e-mail is from John Gray
23 to -- is it Paul Julian dated Tuesday,
24 October 30th, 2007, and then John Gray

1 Do you see that?

2 A. Yes. That's what it says,
3 yes.

4 Q. Turn to the third page of
5 the document, of the -- the slides. So
6 it's technically the fourth page of the
7 document. "Suspicious orders - policy
8 questions" is the heading of the slide.

9 Do you see that?

10 A. I do.

11 Q. Halfway down the slide it
12 says, "Should we support DEA's efforts?"

13 Do you see that?

14 A. Yes.

15 Q. So there are some questions
16 about whether HDMA and its members were
17 going to support DEA's efforts, correct?

18 A. Yes.

19 MS. MACKAY: Object to form.

20 MR. WEINSTEIN: Objection to
21 form. Just got to give a second
22 after the question.

23 THE WITNESS: Oh, I'm sorry.

24 BY MR. PIFKO:

1 Q. One of the bullet points is,
2 "Develop business practices," which is --
3 business practices is in quote.

4 Do you see that?

5 A. I do.

6 Q. Do you now understand what
7 that refers to?

8 A. I -- I think what it led to,
9 yes.

10 Q. The industry compliance
11 guidelines, correct?

12 A. Yes.

13 Q. And then it says,
14 "Alternatively do we want to challenge
15 DEA's expectations?"

16 Do you see that?

17 A. Yes.

18 Q. And that was something else
19 HDMA and its members were considering at
20 this time, correct?

21 MS. MACKAY: Object to form.

22 THE WITNESS: Again, I think
23 there was a variety of
24 considerations going on at the

1 time, yes.

2 BY MR. PIFKO:

3 Q. But this was one of them,
4 correct?

5 A. According to this, yes.

6 Q. Again, it says, "What are
7 our legal options?"

8 Do you see that?

9 A. I do.

10 Q. So there were some
11 evaluations of what legal strategies can
12 be employed to challenge the DEA's
13 expectations?

14 MR. WEINSTEIN: Objection to
15 form.

16 THE WITNESS: Again, I think
17 those considerations were being
18 discussed.

19 (Document marked for
20 identification as Exhibit
21 HDA-Kelly-7.)

22 BY MR. PIFKO:

23 Q. I'm handing you what's
24 marked as Exhibit 7, it is a two-page

1 webinars and seminars to educate the
2 members and the customers about the
3 guidelines as well"?

4 A. Yes.

5 Q. And Scott also told DEA that
6 "HDA would discuss, explain and encourage
7 acceptance of the guidelines by other
8 trade associations, including
9 manufacturing and pharmacy groups."

10 That's the second bullet
11 point on the page?

12 A. Yes, yes, yes, yes, yes.

13 Q. So you agree, a key message
14 that Scott was communicating to DEA here
15 was that HDA was going to work to make
16 sure its members and other participants
17 in the supply chain in the pharmaceutical
18 industry would implement these
19 guidelines, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: I think we --
23 we meant to basically educate the
24 rest, that they were available.

1 Again, we are not a
2 standards agency, we are not a
3 regulatory authority. We can't
4 basically make any entity comply
5 with the guidelines. We were just
6 going to educate as many folks as
7 we could about their existence and
8 make them available.

9 BY MR. PIFKO:

10 Q. But you told DEA that you
11 wanted to help your members implement the
12 guidelines, correct?

13 MR. WEINSTEIN: Objection to
14 form.

15 THE WITNESS: That's -- yes,
16 that's what it -- that's what it
17 says here, yes.

18 BY MR. PIFKO:

19 Q. Handing you what's marked as
20 Exhibit 24.

21 (Document marked for
22 identification as Exhibit
23 HDA-Kelly-24.)

24 BY MR. PIFKO:

1 Q. It is a three-page e-mail
2 between HDA and AmerisourceBergen.
3 Bates-labeled HDA_MDL_000156499 through
4 156501.

5 Take a minute to review
6 this, and let me know when you're done.

7 There is some discussion
8 about whether Chris Zimmerman from
9 AmerisourceBergen is going to serve as
10 a -- a chairman of a committee. I'm not
11 interested in that part of the discussion
12 here.

13 A. Okay.

14 Q. This goes back to earlier in
15 the process of developing the industry
16 compliance guidelines or best practices,
17 agree, it's back in early January 2008?

18 A. Yes.

19 Q. And this is before this
20 meeting with DEA, correct?

21 A. It is.

22 Q. Okay. And in this e-mail on
23 the first page, 156499, Mr. Zimmerman
24 tells HDA's Anita Ducca, "I think we need

1 to discuss the suspicious order project.
2 Since ABC has an agreement with DEA, it
3 does not matter what best practices HDMA
4 develops because ABC must adhere to its
5 written agreement with DEA. I assume
6 Cardinal will be in the same boat.
7 Therefore, I'm not sure what benefit ABC
8 would receive from this project."

9 Do you see that?

10 A. I do.

11 Q. Did I read that correctly?

12 A. You do.

13 Q. Okay. So you agree that at
14 this time Mr. Zimmerman is saying that
15 he's not going to implement any
16 guidelines or best practices, and he
17 assumes Cardinal is not going to either,
18 correct?

19 MS. ROLLINS: Object to
20 form.

21 MR. WEINSTEIN: Objection to
22 form. Foundation.

23 THE WITNESS: I think what
24 he's implying is that they are

1 already under strict adherence to
2 a specific plan with -- directly
3 with the DEA that satisfies their
4 obligations. But it's specific to
5 those companies individually,
6 therefore, a model plan or
7 guidelines is irrelevant for them.

8 BY MR. PIFKO:

9 Q. And they have no plan on
10 implementing them at this time, correct?

11 MS. ROLLINS: Objection to
12 form.

13 MR. WEINSTEIN: Objection to
14 foundation and form.

15 THE WITNESS: Because they
16 have their own policies in place.

17 BY MR. PIFKO:

18 Q. You said here that they have
19 a plan that satisfies the DEA. Where
20 does it say that it satisfies the DEA?

21 A. I'm deducing from this
22 document that since ABC has an agreement
23 with DEA, it does not matter what best
24 practices HDMA develops because ABC must

1 adhere to its written agreement with DEA.

2 Q. What about Cardinal?

3 MR. WEINSTEIN: Objection to
4 form.

5 MS. CHARLES: Objection to
6 form.

7 BY MR. PIFKO:

8 Q. It doesn't say anything like
9 that about Cardinal, does it?

10 MR. WEINSTEIN: Objection to
11 form. Foundation.

12 THE WITNESS: An individual
13 from ABC insinuates that Cardinal
14 may be a similar position due to
15 a -- maybe a consent decree that
16 Cardinal entered into with DEA as
17 well that would be in the same
18 constriction with regard to their
19 practices that ABC is at the time.

20 BY MR. PIFKO:

21 Q. And so the HDA knew this
22 information before it had the meeting
23 with DEA, correct?

24 A. Obviously we were apprised

1 that they were basically not going to be
2 of help in developing the guidelines or
3 adopting the guidelines, because they are
4 there are under a separate agreement.

5 Q. Do you know if
6 AmerisourceBergen ever asked DEA if it
7 could follow the guidelines as an
8 improvement on measures it was already
9 engaged in?

10 MS. ROLLINS: Objection to
11 form.

12 MR. WEINSTEIN: Objection to
13 form. Foundation.

14 THE WITNESS: I do not.

15 BY MR. PIFKO:

16 Q. No one ever told you that
17 they had requested anything from DEA as
18 far as being able to implement the
19 industry compliance guidelines?

20 MS. ROLLINS: Objection to
21 form.

22 THE WITNESS: That ABC had
23 requested? Again, I don't know.

24

1 BY MR. PIFKO:

2 Q. Same question about Cardinal
3 Health.

4 MS. CHARLES: Objection to
5 form.

6 THE WITNESS: Again I don't
7 know. I don't know.

8 BY MR. PIFKO:

9 Q. To your knowledge, did any
10 distributor implement the industry
11 compliance guidelines?

12 MR. WEINSTEIN: Objection to
13 form. Foundation.

14 THE WITNESS: Again, I don't
15 know. They were -- they were
16 guidelines. Many of the
17 companies, from what I understand,
18 already had various processes in
19 place. These guidelines were
20 developed to better inform them
21 about expectations within the DEA.
22 And if they -- they could beg and
23 borrow, and again it was meant to
24 be kind of something that could be

1 applicable to various size
2 companies and be able to adapt.

3 So again I don't know if
4 anybody adopted the entire
5 document verbatim or not. And we
6 didn't ask.

7 BY MR. PIFKO:

8 Q. You don't know if anybody
9 adopted parts of the document either,
10 correct?

11 MR. WEINSTEIN: Objection to
12 form.

13 THE WITNESS: We don't.

14 BY MR. PIFKO:

15 Q. So sitting here today, you
16 don't know, and at no time does HDMA know
17 if any members or other distributors
18 adopted all or part of the industry
19 compliance guidelines, correct?

20 MR. WEINSTEIN: Objection to
21 form.

22 THE WITNESS: I don't know,
23 nor did we ask. And again, I
24 stated before, we are not a

1 regulatory authority; we are not a
2 standard-setting body. We are
3 simply doing our best to inform
4 our members about existing
5 policies.

6 BY MR. PIFKO:

7 Q. And to your knowledge, no
8 pharmaceutical manufacturer ever adopted
9 the industry compliance guidelines or any
10 portion of them, correct?

11 MR. WEINSTEIN: Objection to
12 form.

13 MS. MACKAY: And foundation.

14 THE WITNESS: And again,
15 they were not -- they were not
16 developed for manufacturers. They
17 were developed for our core
18 members, the distributor members
19 of HDA.

20 BY MR. PIFKO:

21 Q. But you did discuss them
22 with the Pain Care Forum, which included
23 manufacturers, correct?

24 MR. WEINSTEIN: Objection to

1 BY MR. PIFKO:

2 Q. For the record Exhibit 33 is
3 a Word document that was -- file name --
4 name GAO Meeting on DEA Draft, TPs,
5 092010. It's Bates-labeled HDMA -- or
6 sorry, HDA_MDL_000139905 to 000139910.
7 Take a minute to review it and let me
8 know when you're done.

9 A. Okay.

10 Q. You done?

11 A. Yes.

12 Q. So if you recall, we were
13 looking earlier at a document, that
14 document about the strategy for testimony
15 on the Hill. Do you recall that?

16 A. Yes, I do.

17 Q. And one of the tactics that
18 was discussed there was getting a
19 congressperson to talk to the DEA to
20 address the industry's concerns. Do you
21 recall that?

22 A. I do.

23 Q. Another tactic that HDA was
24 considering was communicating with the

1 Government Accountability Office about
2 the -- its concerns about the DEA,
3 correct?

4 MR. WEINSTEIN: Objection to
5 form.

6 THE WITNESS: I don't know
7 if that was part of that. I
8 didn't -- was that part of that?

9 BY MR. PIFKO:

10 Q. Irrespective of that
11 document, I'm just asking you --

12 A. It is --

13 Q. -- if that was another
14 tactic that HDA was investigating?

15 MR. WEINSTEIN: Objection to
16 form.

17 THE WITNESS: Again, we
18 don't have the ability to launch
19 GAO investigations, but we can
20 talk to members of Congress who
21 may think that's a correct course
22 of action.

23 BY MR. PIFKO:

24 Q. Okay. And so that was

1 something that HDA was exploring about
2 whether there could be a dialogue with
3 GAO about the industry's concerns about
4 the DEA, correct?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: Again I don't
8 know if we -- if we specifically
9 requested that. I know that this
10 GAO report was requested by
11 members of Congress.

12 BY MR. PIFKO:

13 Q. Okay. These are talking
14 points about the industry's concerns that
15 would be presented at the GAO, correct?

16 A. Correct.

17 Q. So, this talks about, I'm on
18 the second page of the document. It
19 first says, "Background on HDMA, who we
20 represent, show the graphic of wholesale
21 distribution we have online, number of
22 members, et cetera."

23 So in connection with the
24 discussion, there would have been a

1 discussion about who the members are that
2 are represented by HDA, correct?

3 MR. WEINSTEIN: Objection to
4 form.

5 THE WITNESS: Yes.

6 BY MR. PIFKO:

7 Q. And then this identifies
8 recent concerns. Do you see that
9 discussion in Section 4 here?

10 A. Yes, I see Section 4.

11 Q. It says, "Recently DEA has
12 exerted extreme pressure on wholesale
13 distributors to take controlled
14 substances suspicious order
15 responsibilities much further."

16 Do you see that?

17 A. I do.

18 Q. Do you agree that was a
19 concern from HDA and its distributor
20 members?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: It was.

24 BY MR. PIFKO:

1 Q. And then it gives bullet
2 points elaborating on that concern,
3 agree?

4 A. It appears to, yes.

5 Q. And the first one is, "DEA
6 invited members of the distribution
7 industry, firm by firm to a meeting where
8 DEA point blank told them that they
9 should identify customers who are selling
10 for illicit purposes, e.g., pill mills, or
11 illicit internet pharmacies such as those
12 filling orders without a prescription."

13 Do you see that?

14 A. I do.

15 Q. So that was part of the
16 basis for the HDA and its members'
17 concerns about DEA's pressures to take
18 controlled substances order
19 responsibilities further?

20 MS. WICHT: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, that

1 was -- that was an event or a
2 process that DEA had undertaken.
3 I have no reason to doubt that
4 that was part of the pattern of
5 concern.

6 BY MR. PIFKO:

7 Q. And then another part of
8 that concern was that that action was
9 followed by revoking several
10 registrations in 2007, agreed?

11 A. That's what is stated, yes.

12 Q. And then it says, "HDA went
13 to great lengths to seek resolution with
14 DEA." And then it's got some bullet
15 points. Some of them are discussing the
16 industry compliance guidelines we just
17 discussed, agree?

18 A. Yes.

19 Q. And then in all bold, all
20 caps, it says, "Despite these efforts,
21 DEA has revoked another wholesale
22 distributor registration spring 2010."

23 Do you see that?

24 A. I do.

1 Q. So the DEA's revoking or
2 suspending registrations, was a
3 significant concern for HDA and its
4 members?

5 MR. WEINSTEIN: Objection to
6 form.

7 THE WITNESS: Yes.

8 BY MR. PIFKO:

9 Q. If you go to the page --
10 they are not numbered here --
11 HDA_MDL_000139907. There's a heading,
12 "Key Concerns."

13 A. I see it.

14 Q. So this summarizes key
15 concerns that HDA and its members had
16 with respect to the DEA's enforcement
17 activities, correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 THE WITNESS: Yes, at the
21 time.

22 BY MR. PIFKO:

23 Q. So one of them is, it says,
24 "It's unreasonable for DEA to expect a

1 distributor to seek information about
2 pharmacies that they are barred from,
3 either through confidential business
4 practices or legal restrictions, e.g.,
5 HIPAA."

6 Do you see that?

7 A. Yes, I do.

8 Q. That was a key concern?

9 MS. CHARLES: Objection to
10 form.

11 THE WITNESS: Again, this
12 means that they were unreasonable
13 for DEA to expect distributors to
14 get prescribing information that
15 would have been HIPAA protected.

16 BY MR. PIFKO:

17 Q. And then it says under here,
18 "DEA has asked distributors where
19 pharmacies' prescriptions came from, also
20 to research the pharmacies' customer
21 base.

22 So was that -- that was the
23 basis for that concern?

24 A. I think that's part of the

1 concern, yes.

2 Q. Then it says, "Even if the
3 distributor does their due diligence
4 regarding a customer, there's no
5 guarantee that the pharmacy will tell the
6 truth."

7 That was another concern?

8 A. That is -- that is a
9 concern, yes.

10 Q. Then here it says, again,
11 "DEA used an extreme tactic by suspending
12 a license. This action is intended for
13 when there is an imminent threat to the
14 public health and safety."

15 Do you see that?

16 A. Yes.

17 Q. So again, this tactic of
18 suspending or revoking registrations was
19 a critical concern for HDMA and its
20 members, correct?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: Yes.

24 BY MR. PIFKO:

1 BY MR. PIFKO:

2 Q. I'm handing you what's
3 marked as Exhibit 35. It's an e-mail
4 from you dated December 19, 2013,
5 Bates-labeled CAH_MDL2804_01110712
6 through 715.

7 Take a moment to review this
8 and let me know when you're done.

9 A. Okay.

10 Q. At some point a drug
11 diversion DEA strategy task force was
12 formed, correct?

13 A. Yes.

14 Q. Are you familiar with the
15 formation of that task force?

16 A. I am.

17 Q. Were you involved in the
18 formation of that task force?

19 A. We were. I was.

20 Q. When was that formed?

21 A. I want to say in 2013 at
22 some point. It was a amalgam of a
23 variety of different committees that had
24 been involved. Regulatory affairs

1 committee, federal government affairs
2 committee, individuals, and then to
3 basically brainstorm some suggestions for
4 additional things that we could do to
5 continue to move forward on addressing
6 suspicious orders and improving
7 interaction with the DEA.

8 Q. So that task force is an
9 outcrop of some of the types of
10 discussions that you had in Exhibit 34?

11 A. Yeah. It's not specifically
12 referenced here. But yeah, it's just an
13 ongoing discussion and dialogue with the
14 membership about what we can do to
15 improve.

16 Q. Who was on that task force
17 as far as the HDA's distributor members?

18 A. So if you look at the top,
19 AmerisourceBergen, Cardinal Health,
20 Mutual Drug, Smith Drug, HD Smith, Henry
21 Schein, I think was at one point
22 involved.

23 Q. McKesson?

24 A. McKesson, sorry, yes. And

1 then we had a -- after we had engaged
2 APCO at the time there, they came and
3 participated.

4 Q. And so you had regular
5 meetings with this task force?

6 A. This -- I believe this task
7 force met once.

8 Q. Okay. And so this is a list
9 of action items that came out of the task
10 force meeting?

11 A. Recommendations, yes.

12 Q. Okay. And then the attached
13 document, summary of recommendations?

14 A. Right.

15 Q. From December 11, 2013, task
16 force meeting. That's a summary of the
17 items that the group came up with that
18 you could move forward with?

19 MR. WEINSTEIN: Objection to
20 form.

21 THE WITNESS: Yes.

22 Sorry.

23 Yes, with the -- the
24 specific action items highlighted.

1 BY MR. PIFKO:

2 Q. And you typed this up?

3 A. I believe I typed the
4 e-mail, and then the notes were kind of
5 probably a shared product of the
6 government affairs staff that
7 participated.

8 Q. Okay. But you ultimately
9 sent it out to everybody?

10 A. I sent it out, yes.

11 Q. Did you have an official
12 title or role with this task force, like
13 chairman or --

14 A. No.

15 Q. -- coordinator?

16 A. No, there was -- and again
17 it was an ad hoc group of various
18 members. It was set up to do one thing,
19 and this was the one thing.

20 Q. So going to the attachment,
21 CAH_MDL2804_01110714. Are you there?

22 A. I am.

23 Q. So Item 2 is, "Address
24 specific challenges and interactions

1 with" -- "with DEA."

2 Do you see that?

3 A. Yes.

4 Q. So you have this broken out
5 into different types of communications
6 like one with the media, public
7 officials, another with DEA, and another
8 with a branding campaign; is that
9 correct?

10 MR. WEINSTEIN: Objection to
11 form.

12 THE WITNESS: Yeah.

13 BY MR. PIFKO:

14 Q. Okay. Sorry, I pointed you
15 to 2, but I want to ask you about 1 for a
16 minute.

17 A. Okay.

18 Q. So in 1, there's a
19 discussion about joining with various
20 other industry groups?

21 A. Mm-hmm.

22 Q. Is that correct?

23 A. Yes.

24 Q. Okay. What's the Alliance

1 to Prevent Abuse of Medicines?

2 A. That was a coalition that
3 formed, I want to say in about 2012, to
4 address abuse issues, kind of across the
5 supply chain. So they had formed -- the
6 American Medical Association, the members
7 that were listed there were participants.
8 Cardinal Health had suggested possibly
9 including HDA as a member, because other
10 associations were involved.

11 THE VIDEOGRAPHER:

12 Mr. Kelly, you keep hitting --

13 THE WITNESS: I'm sorry.

14 BY MR. PIFKO:

15 Q. So then Item 2 says,
16 "Address specific challenges and
17 interactions with DEA."

18 Do you see that?

19 A. I do.

20 Q. Then it says, "Issue
21 statement of support for Marino/Blackburn
22 legislation when introduced."

23 Do you see that?

24 A. I do.

1 Q. Okay. So that hadn't yet
2 been introduced at this time?

3 A. I don't know the specific
4 introduction date, but I would deduce
5 from this that obviously it had not.

6 Q. Okay. Was the -- that
7 legislation drafted out of the HDMA?

8 A. No. I believe
9 Mr. Blackburn -- or I'm sorry, Mr. Marino
10 was moving forward with that issue, had
11 requested feedback from a variety of
12 constituencies, and was in the process of
13 kind of fleshing it out.

14 Q. When was the first time you
15 became aware of that bill or that
16 legislation?

17 A. It -- it might have been at
18 this -- at this meeting. One of our
19 member companies had been contacted by
20 Mr. Marino about participating in the --
21 in the kind of the general drafting
22 process of -- of that bill. And it was
23 suggested that we -- we work with -- or
24 HDA work with Congressman Marino and

1 Congresswoman Blackburn.

2 Q. Do you know which member
3 company it was?

4 A. It was Cardinal.

5 Q. Okay. So Mr. Marino had
6 reached out to Cardinal and asked them to
7 assist in drafting this bill?

8 A. That's my understanding.

9 Q. And then they reached out to
10 you and asked HDA to participate?

11 A. They did.

12 Q. And did HDA end up providing
13 any drafting on the bill?

14 A. We provided feedback on
15 drafts that they -- they would -- that
16 they would basically share drafts with
17 us. I don't know if it was in advance of
18 the actual introduction. But they go
19 through iterative processes of kind of
20 taking comments and providing subsequent
21 drafts. We did participate in that
22 process.

23 Q. Do you know who -- who
24 specifically at Cardinal did you interact

1 with on that issue?

2 MS. WICHT: Objection to
3 form.

4 THE WITNESS: Connie
5 Woodburn was the government
6 affairs person for Cardinal at the
7 time.

8 BY MR. PIFKO:

9 Q. Okay. But did you interact
10 with anyone else from Cardinal?

11 A. Not specifically with regard
12 to this.

13 Q. Okay. Did -- do you -- do
14 you know, were there other people who
15 maybe you didn't talk to but that would
16 have been copied on e-mails or there are
17 things would have been forwarded from
18 Cardinal with respect to the
19 Marino/Blackburn bill?

20 MS. WICHT: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form, foundation, scope.

24 THE WITNESS: I can't say

1 for certain.

2 BY MR. PIFKO:

3 Q. Do you know if Linden Barber
4 was involved in the Marino/Blackburn
5 bill?

6 MR. WEINSTEIN: Same
7 objections.

8 MS. WICHT: Object to form.

9 THE WITNESS: I don't know
10 initially. It was a multi-year
11 process.

12 BY MR. PIFKO:

13 Q. Do you know if any other HDA
14 distributor members were involved in
15 discussions with Marino at that time
16 concerning the bill?

17 MS. WICHT: Objection to
18 form.

19 MR. WEINSTEIN: Objection to
20 form, foundation, scope.

21 THE WITNESS: At that time I
22 do not.

23 BY MR. PIFKO:

24 Q. How about later?

1 MS. WICHT: Objection to
2 form.

3 MR. WEINSTEIN: Same
4 objections.

5 THE WITNESS: Well, as soon
6 as -- as soon as HDA basically
7 endorsed the -- the initiative, I
8 think the entire membership was
9 supportive of the -- the prospect
10 of that legislation.

11 BY MR. PIFKO:

12 Q. Okay. And obviously the
13 entire member -- or the -- the members we
14 just discussed here having been involved
15 with this drug diversion task force all
16 knew about it because it was discussed at
17 this meeting, correct?

18 MR. WEINSTEIN: Objection to
19 form.

20 MS. WICHT: Foundation.

21 THE WITNESS: Correct.

22 BY MR. PIFKO:

23 Q. So it says here, "This
24 legislation would establish definitions

1 and parameters for specific provisions in
2 the Controlled Substances Act pertaining
3 threats to 'public health and safety' and
4 'imminent danger.'

5 "In addition, this
6 legislation would allow DEA registrants
7 the opportunity to submit a corrective
8 action plan to address specific concerns
9 that could otherwise lead to the
10 suspension or revocation of a
11 registration."

12 Did I read that correctly?

13 A. You did.

14 Q. Is that consistent with your
15 understanding about what this bill would
16 do or legislation would do?

17 MR. WEINSTEIN: Objection to
18 form.

19 THE WITNESS: It is. There
20 was another provision ultimately
21 of the bill. But it was a
22 draft -- a report from the
23 government on the effectiveness of
24 the government's efforts to

1 address prescription drug abuse
2 and diversion.

3 BY MR. PIFKO:

4 Q. Okay. So it's your
5 understanding there were changes to the
6 requirements for suspending a
7 registration, and there was another
8 component to the legislation that
9 involved a report?

10 MR. WEINSTEIN: Objection to
11 form.

12 BY MR. PIFKO:

13 Q. Is that correct?

14 MR. WEINSTEIN: Same
15 objection.

16 THE WITNESS: So, basically
17 the crux of it was to provide a
18 definition for the threshold for
19 immediate suspension orders.
20 Which was not anywhere in law.
21 The immediate -- the immediate --
22 imminent danger was not defined.
23 And so we basically sought to
24 establish a threshold for what

1 constitutes imminent danger.

2 BY MR. PIFKO:

3 Q. If we go to the next page of
4 your notes. Another action item that
5 this task force was working on was Item
6 D, "Anticipate and develop responses to
7 Marino/Blackburn opponents"?

8 A. I see that.

9 Q. That was something that this
10 task force was working on, correct?

11 A. Well, again, it wasn't one
12 of the action items. But it was -- it
13 basically was something that we
14 discussed. It was, you know, how do
15 we -- how do we explain what this does if
16 people are concerned that it's somehow
17 diminishing the capacity of the DEA.

18 Q. Item 3 here is, "Engage in
19 initial HDMA public relations branding
20 campaign."

21 Do you see that?

22 A. I do.

23 Q. Item C there says, "Utilize
24 material prepared by APCO to begin

1 targeted media outreach."

2 Do you see that?

3 A. I do.

4 Q. That's the material that
5 includes the crisis playbook, correct?

6 MR. WEINSTEIN: Objection to
7 form.

8 THE WITNESS: Again, I'm not
9 exactly sure. The crisis playbook
10 was never -- it was a draft format
11 that was never released. It was
12 never published. It was -- we
13 didn't do anything with it. But
14 that was a product that APCO did
15 provide us in their initial
16 engagement.

17 BY MR. PIFKO:

18 Q. Okay. And you shared that
19 product with the HDA's members, correct?

20 MS. CHARLES: Objection to
21 form.

22 MR. WEINSTEIN: Objection to
23 form.

24 THE WITNESS: Again, I don't

1 recall. Our communications
2 department handled all that
3 interface with APCO.

4 BY MR. PIFKO:

5 Q. You wouldn't have any reason
6 to dispute that it was shared with
7 members?

8 MR. WEINSTEIN: Objection to
9 form.

10 MS. CHARLES: Objection to
11 form.

12 MS. ROLLINS: Objection to
13 form.

14 THE WITNESS: I can't say
15 one way or another.

16 BY MR. PIFKO:

17 Q. You would agree if it was
18 produced by one of the members in this
19 litigation, it must have been shared with
20 them obviously, right?

21 MR. WEINSTEIN: Objection to
22 form.

23 THE WITNESS: Yes.
24

1 Q. I'm handing you what's
2 marked as Exhibit 39.

3 (Document marked for
4 identification as Exhibit
5 HDA-Kelly-39.)

6 BY MR. PIFKO:

7 Q. This document is not
8 Bates-labeled. We printed it from HDA's
9 website. Take a moment to review it.

10 For the record, it's a
11 document that is identified on the first
12 page as "Statement from John Gray,
13 President and CEO, Healthcare
14 Distribution Management Association For
15 the U.S. House of Representatives Energy
16 and Commerce Committee, Subcommittee on
17 Health," dated April 7, 2014. It's a
18 five-page document.

19 Have you seen this before?

20 A. I have.

21 Q. Did you assist in preparing
22 this testimony?

23 A. I did.

24 Q. And this is testimony that

1 Mr. Gray provided for the House of
2 Representatives energy and commerce
3 committee subcommittee on health --

4 A. It --

5 Q. -- from April 7, 2014?

6 A. It is.

7 Q. These are statements that he
8 made before that committee?

9 A. This is the written
10 statement. I don't know how much it
11 deviated from the oral statement.

12 Q. Okay. And you participated
13 in -- in writing this?

14 A. I helped to prepare it, yes.

15 Q. Okay. Anyone else?

16 A. The whole government affairs
17 team. Probably our communication team as
18 well.

19 Q. And in this he's discussing,
20 the Marino/Blackburn bill, correct?

21 A. Yes.

22 Q. Second sentence, "Thank you
23 for the opportunity to discuss with the
24 subcommittee important legislation

1 introduced by Representatives Blackburn
2 and Marino, the Ensuring Patient Access
3 and Effective Drug Enforcement Act of
4 2014," correct?

5 A. Yes.

6 Q. Then the next paragraph,
7 second sentence, he says, "Our industry's
8 primary mission is to operate the safest
9 and most secure and efficient supply
10 chain in the world."

11 Agree with that statement?

12 A. I do.

13 Q. "As part of this mission,
14 the pharmaceutical industry is committed
15 to addressing the serious national
16 epidemic of prescription drug abuse."

17 Do you see that?

18 A. I do.

19 MR. WEINSTEIN: You missed
20 the word "distribution" in there,
21 you missed.

22 MR. PIFKO: Sorry. I'll
23 read it again for the record.

24 BY MR. PIFKO:

1 Q. To be clear, so Mr. Gray
2 testified before this committee and said
3 that "the pharmaceutical distribution
4 industry is committed to addressing the
5 serious national epidemic of prescription
6 drug abuse," correct?

7 A. Yes.

8 Q. Next paragraph. Mr. Gray
9 also told the committee, "HDMA's members
10 are committed to working proactively with
11 DEA," correct?

12 A. Yes.

13 Q. Page 2 of the testimony. He
14 says, "This is one of the reasons" --
15 second full paragraph. "This is one of
16 the reasons why HDMA supports HR 4069."

17 That's the Marino/Blackburn
18 bill, correct?

19 A. Yes.

20 Q. He says this -- he told the
21 committee, "This legislation is a timely
22 and thoughtful approach to addressing the
23 prescription drug epidemic," correct?

24 A. Yes.

1 Q. And he said, "We will
2 believe it will foster greater
3 collaboration, communication and
4 transparency between" -- "between
5 industry stakeholders and regulators,
6 especially the DEA," correct?

7 A. Correct.

8 Q. And then in the next
9 paragraph he talks about establishing a
10 collaborative working relationship with
11 the DEA.

12 Do you see that?

13 A. Yes.

14 Q. And he provided that
15 testimony to the subcommittee as well,
16 correct?

17 A. Yes.

18 (Document marked for
19 identification as Exhibit
20 HDA-Kelly-40.)

21 BY MR. PIFKO:

22 Q. I'm handing you what's
23 marked as Exhibit 40. It's an e-mail
24 from you to Ann Berkey of McKesson,

1 final version of that legislation.

2 MR. WEINSTEIN: We've been
3 going about an hour.

4 MR. PIFKO: We'll take a
5 break in about two seconds.

6 BY MR. PIFKO:

7 Q. I want to turn your
8 attention back to Exhibit 31 to Page 11
9 and 12. I want to direct you to language
10 on Page 12, but 11 tells you that this
11 was a discussion that occurred at the
12 September 28, 2015, board of directors
13 meeting. Turn to Page 12. Tell me when
14 you're ready.

15 A. Okay.

16 Q. During this September 28,
17 2015, board of directors meeting,
18 "President Gray noted HDMA executive
19 committee had discussed and agreed to
20 prioritize objectives on prescription
21 drug abuse in the following order: Item
22 Number 1, exhaust all efforts to secure
23 passage of S.483."

24 Do you see that?

1 A. On -- which page are you on?

2 Q. 12.

3 A. Oh, yes. Okay, I see it.

4 Q. Did I read that correctly?

5 A. "Exhaust all efforts to
6 secure passage of S.483." Yes.

7 Q. So S.483 is the final
8 version that got passed?

9 A. It was, yes, the bill that
10 got passed by the senate and approved
11 unanimously both -- in both chambers and
12 signed by President Obama.

13 MR. PIFKO: Okay. We can
14 take a break.

15 THE VIDEOGRAPHER: The time
16 is 3:51 p.m. We are going off the
17 record.

18 (Short break.)

19 THE VIDEOGRAPHER: The time
20 is 4:11 p.m. We are back on the
21 record.

22 (Document marked for
23 identification as Exhibit
24 HDA-Kelly-41.)